

## การพัฒนาร้านขายยาแผนปัจจุบันเฉพาะยาบรรจุเสร็จที่ไม่ใช่ยาอันตรายหรือยาควบคุมพิเศษ (ข.ย.2) สู่มาตรฐานตามหลักวิธีปฏิบัติทางเภสัชกรรมชุมชน (GPP) ในจังหวัดอุดรธานี

ปรกช โคมุทกลาง

กลุ่มงานคุ้มครองผู้บริโภคและเภสัชสาธารณสุข, สำนักงานสาธารณสุขจังหวัดอุดรธานี

\* ติดต่อผู้พิมพ์: porakoch.km@gmail.com

### บทคัดย่อ

การพัฒนาร้านขายยาแผนปัจจุบันเฉพาะยาบรรจุเสร็จที่ไม่ใช่ยาอันตรายหรือยาควบคุมพิเศษ (ข.ย.2) สู่มาตรฐานตามหลักวิธีปฏิบัติทางเภสัชกรรมชุมชน (GPP) ในจังหวัดอุดรธานี

ปรกช โคมุทกลาง

ว. เภสัชศาสตร์อีสาน 2566; 19(4) : 61-74

รับบทความ: 13 กรกฎาคม 2566

แก้ไขบทความ: 20 กันยายน 2566

ตอบรับ: 16 ตุลาคม 2566

จากประกาศกระทรวงสาธารณสุข กำหนดวิธีปฏิบัติทางเภสัชกรรมชุมชน (GPP) ในร้านยา ข.ย. 2 ที่ทุกร้านต้องปฏิบัติตามและผ่านการประเมินในการต่ออายุใบอนุญาต เพื่อสำรวจสถานการณ์ความรู้ความเข้าใจของผู้ประกอบการและความพร้อมของร้านยา ข.ย. 2 ตามเกณฑ์ GPP รวมถึงผลการพัฒนาร้านขายยาตามแนวทางที่กำหนดขึ้นอย่างมีส่วนร่วม วิธีดำเนินการวิจัย: การวิจัยเชิงปฏิบัติการแบบมีส่วนร่วมของร้านยา ข.ย.2 ในจังหวัดอุดรธานีทั้งหมด 40 แห่ง โดยใช้วงจร PAOR ได้แก่ การวางแผน การปฏิบัติ การสังเกต และการสะท้อนผล เก็บข้อมูลความสอดคล้องแบบประเมินตนเองของผู้ประกอบการกับพนักงานเจ้าหน้าที่จากแบบประเมิน GPP ทั้งหมด 5 หมวด วิเคราะห์ข้อมูลโดยสถิติ Kappa เปรียบเทียบคะแนนเฉลี่ยก่อนและหลังการพัฒนาตามแนวทางที่กำหนดโดยสถิติ Paired T-test ทั้งนี้เก็บข้อมูลเชิงคุณภาพจากการประชุมกลุ่มกำหนดแนวทางร่วมกันที่ผ่านการตรวจสอบสามเส้าด้านข้อมูล วิเคราะห์ข้อมูลโดยใช้ Content analysis ผลการศึกษา: สถานการณ์ความรู้ความเข้าใจของผู้ประกอบการร้านยา ข.ย.2 จากผลการประเมินตนเองกับพนักงานเจ้าหน้าที่ที่มีความแตกต่างกัน โดยความสอดคล้องของแบบประเมินอยู่ในระดับพอใช้ถึงไม่สอดคล้องกัน ส่วนความพร้อมของร้านยาตามเกณฑ์ GPP พบว่า หมวด 3 บุคลากร มีความพร้อมมากที่สุด และหมวด 4 คุณภาพยา มีความพร้อมน้อยที่สุด ปัญหาส่วนมากที่พบ คือ ผู้ประกอบการมีความเข้าใจเกณฑ์การประเมินและกฎหมายด้านยาที่ไม่ถูกต้อง รวมถึงการเข้าถึงข้อมูลสารสนเทศที่จำเป็น กำหนดเป็นแนวทางพัฒนา ดังนี้ 1) การประชุมพัฒนาร้านยาตามเกณฑ์ GPP อย่างมีส่วนร่วม 2) สนับสนุนเอกสาร 3) จัดทำช่องทางให้คำปรึกษาทางไลน์ออฟฟิเชียล ทั้งนี้จากการประชุมกลุ่มผู้ประกอบการเห็นด้วยกับแนวทางพัฒนาที่เป็นมาตรฐานเดียวกันทั้งจังหวัด โดยสามารถดำเนินการให้ครบถ้วน ภายใน 2 เดือน ผลการพัฒนาพบว่าร้านยามีคะแนนเฉลี่ยในแต่ละหมวดและคะแนนเฉลี่ยรวม 5 หมวด เพิ่มขึ้นอย่างมีนัยสำคัญทางสถิติ ( $p < 0.05$ ) สรุป: การพัฒนาร้านยาอย่างมีส่วนร่วมทุกขั้นตอน โดยการสร้างความเข้าใจ แลกเปลี่ยนความคิดเห็นซึ่งกันและกัน รวมทั้งให้คำปรึกษาอย่างใกล้ชิดผ่านระบบออนไลน์ ทำให้ร้านยา ข.ย.2 สามารถผ่านเกณฑ์ GPP สำเร็จทั้งหมด ทั้งนี้สามารถนำแนวทางพัฒนาในครั้งนี้ไปปรับใช้ตามบริบทในพื้นที่ต่าง ๆ อย่างมีประสิทธิภาพต่อไป

คำสำคัญ: ร้านยา ข.ย.2, ร้านขายยาแผนปัจจุบันเฉพาะยาบรรจุเสร็จไม่ใช่ยาอันตรายหรือยาควบคุมพิเศษ, การพัฒนาร้านขายยา, วิธีปฏิบัติทางเภสัชกรรมชุมชน, GPP



## The Development of Modern Drugstores for Packaged Non-Dangerous or Non-Specially Controlled Drugs (Type 2) to Comply with The Good Pharmacy Practice (GPP) Standards in Udon Thani Province

Porakoch Komutklang

Health Consumer Protection and Pharmacy Department, Udon Thani Provincial Public Health Office, Udon Thani, Thailand

\*Corresponding author: porakoch.km@gmail.com

### Abstract

#### The Development of Modern Drugstores for Packaged Non-Dangerous or Non-Specially Controlled Drugs (Type 2) to Comply with The Good Pharmacy Practice (GPP) Standards in Udon Thani Province.

Porakoch Komutklang

IJPS, 2023; 19(4) : 61-74

Received: 13 July 2023

Revised: 20 September 2023

Accepted: 16 October 2023

According to the Notification of Ministry of Public Health on Good Pharmacy Practice (GPP) Criteria in Type 2 Drugstores, all Type 2 drugstores need to be compliant and pass the assessment for license renewal. The objectives of this research were to survey the situation of Type 2 drugstore entrepreneurs' knowledge & understanding and readiness according to the GPP criteria, and the results from implementing the development guidelines with participation. **Methods:** This participation action research (PAR) for developing all 40 Type-2 drugstores in Udon Thani Province used the PAOR cycle in 4 steps: Planning, Acting, Observing, and Reflecting. The data on consistency between self-assessment of entrepreneurs and officers were collected by using the GPP assessment form in 5 categories. The data were analyzed by using the Kappa statistics, and the mean comparison between before and after receiving the development guidelines was performed by using paired t-test. Furthermore, qualitative data were gathered through focus group discussions to collaboratively determine the guidelines through validation of data triangulation, and content analysis was used for data analysis. **Results:** According to the self-assessment, knowledge and understanding of Type 2 drugstore entrepreneurs were different from the officers at the fair consistency level to the inconsistency level. Regarding the drugstore readiness according to GPP criteria, Category 3 of personnel was at the highest readiness level while Category 4 of drug quality was at the least readiness level. The problems mostly found were entrepreneurs' incorrect knowledge and understanding about the assessment criteria and drug laws, and difficulty to access necessary information. Accordingly, the guidelines for development were determined to 1) arrange meetings for participatory development of the drugstores according to the GPP criteria, 2) support documents, and 3) arrange an online channel for giving advice through Line Official. After exchanging opinions in the focus group, the entrepreneurs agreed for the development guidelines to be in the same standards throughout the province, and the drugstores would manage to be compliant within 2 months. The results of the development showed that the drugstores' mean score of each category and the total mean score of 5 categories increased with statistical significance ( $p < 0.05$ ). **Conclusion:** The drugstore development with participation in all steps can create understanding, exchange opinions together, and closely give advices through the online systems. As a result, all Type 2 drugstores are successfully compliant to the GPP criteria. These development guidelines can be further applied effectively in other contexts of areas.

**Keywords:** Type 2 drugstores, Modern Drugstores for Packaged Non-Dangerous or Non-Specially Controlled Drugs, development of drugstores, Good Pharmacy Practice Criteria, GPP



## Introduction

A drugstore is a place that provides health services closely to people and the community as a primary form of treatment. It is an option for consumers due to its easy accessibility, convenience, and prompt service within the community. Additionally, it serves as a source of healthcare advice and can refer patients to appropriate physicians (The Office of Community Pharmacy Accreditation Thailand, 2023). In Thailand, drugstores are classified according to the Drug Act B.E. 2510 (1967) into four types based on their licenses to sell modern drugs: modern drugstore (Type 1), modern drugstore for packed non-dangerous or non-specially controlled drugs (Type 2), modern drugstore for packed animal drugs (Type 3), and wholesale modern drugstore (Type 4) (Drug Act, B.E. 2510). The primary purposes of this classification are to control, supervise, and monitor drugstores to ensure quality and standards. The Ministry of Public Health issued the Ministerial Regulation on Application for License and Issuance for License to Sell Modern Drugs B.E. 2556 (2013), which outlines the criteria, methods, and conditions for license renewal, specifying Good Pharmacy Practice (GPP) as a requirement, along with standards and methods for all types of drugstores to ensure the safe use of pharmaceutical drugs. Furthermore, drugstores are required to meet GPP criteria for license renewal consideration (Public Health Ministerial Regulation, 2013).

Modern drugstores for packed non-dangerous or non-specially controlled drugs (Type 2) are permitted to sell common household drugs, packed non-dangerous or non-specially controlled drugs, and traditional drugs. However, these drugs must be packaged in sealed containers without being repacked or placed in deformed original containers. The examples of Type 2 drugstore practitioners were trainees who completed the drugstore practitioner trainings organized by Food and Drug Administration or midwife and nursing officers etc. Currently, the number of Type 2

drugstores is decreasing due to a shortage of pharmacists available to work in modern drugstores, and the Ministry of Public Health has issued a notification regarding the number of modern drugstores for packed non-dangerous or non-specially controlled drugs in each province. When licensees notify of business dissolution or their licenses are revoked, they are not allowed to establish new drugstores as replacements (Notification of the Ministry of Public Health, 2005). Furthermore, to bring Type 2 drugstores into compliance with the GPP standard, the Ministry of Public Health has issued a ministerial notification on the determination of place, equipment, and pharmaceutical practices in Type 2 drugstores according to the Drug Act B.E. 2564 (2021), which took effect immediately. Licensees are required to comply with all requirements by June 25, 2022, to be eligible for assessment and license renewal consideration. The assessment criteria consist of 5 categories: 1) place, 2) equipment, 3) personnel, 4) drug quality, and 5) pharmaceutical service (Notification from the Ministry of Public Health, 2021). However, the criteria for passing the GPP assessment are the critical defect must not be found and the mean score of each category must not be lower than 70% (Notification from Food and Drug Administration, 2016). Subsequently, the Food and Drug Administration (FDA) issued a Notification on Drug License effective from 2023. Since the mentioned ministerial notification closely coincides with the annual license renewal period at the end of 2022, drugstores are required to conduct self-assessments in accordance with the GPP requirements for license renewal and prepare for the 2023 assessment (Notification from the Food and Drug Administration, 2022)."

According to the information from the Medicine Regulation Division in the Food and Drug Administration regarding drug business licenses in 2022, there are 22,025 modern drugstores in Thailand, with 2,146 of them being



Type 2 drugstores (9.74%). Udon Thani is a province in Health Region 8, which has the largest number of drugstores, including the highest number of Type 2 drugstores, totaling 323 modern drugstores and 40 Type 2 drugstores (12.46%) (Medicines Regulation Division of Food and Drug Administration Thailand, 2023). Despite the declining number of Type 2 drugstores, it remains crucial to control, supervise, and monitor them to ensure their quality and standards. Moreover, the GPP assessment criteria are new and have never been implemented before. Drugstores need to acquire knowledge and understanding of the correct and complete assessment criteria. Therefore, the participatory development of Type 2 drugstores to comply with the GPP criteria is essential and necessary for achieving overall development effectiveness and enhancing drugstore quality with full efficiency and sustainability. As a result, the researcher is interested to study the development of the quality of Type 2 drugstores to align with Good Pharmacy Practice (GPP) Criteria in Udon Thani Province. The purposes were to survey the situation of Type 2 drugstore entrepreneurs' knowledge & understanding and readiness according to the GPP criteria, and the results from implementing the development guidelines with participation in order to promote and support legally compliant drugstores, reduce complaints related to drugstores, and enable people to access suitable, safe, and qualified products and healthcare services.

## Materials and Methods

### 1. Study samples and settings

This research is a participatory action research (PAR) aimed at studying the development of all 40 Type-2 licensed drugstores in Udon Thani Province to ensure compliance with the Good Pharmacy Practice (GPP) Criteria. The study has received approval from the Human Research Ethics Committee at the Udon Thani Provincial Public Health Office, with the project code UDREC 7266, granted on April 7th, 2023.

## 2. Instruments

2.1. The quantitative data were collected by using the GPP assessment form with Type 2 drugstores. The assessment has been developed by Medicines Regulation Division of Food and Drug Administration under the Notification of Ministry of Public Health in 5 Categories: 1) place in 8 items, 2) equipment in 4 items, 3) personnel in 5 items, 4) drug quality in 9 items, and 5) pharmaceutical service in 9 items. The full score of each category was 100 points.

2.2 The qualitative data were collected through the focus group by setting the meeting issues through validation of data triangulation from the perspectives of the meeting participants who were entrepreneurs and officers on 1) situations and problems of drugstores according to the GPP criteria, 2) The GPP assessment criteria and requirements, 3) guidelines for drugstore development, and 4) mutual agreement in developing drugstores according to the GPP criteria.

## 3. Data collection

The GPP assessment form was administered to Type 2 drugstores by three officers under the Drug Act B.E. 2510 (1967) affiliated with the Consumer Protection and Pharmaceutical Department of Udon Thani Province. The research procedure and data collection were carried out through collaborative efforts between research participants and entrepreneurs. This was done using the PAOR cycle between April 7th to July 7th 2023, following the concept developed by Kemmis & McTaggart, which consists of four steps (Kemmis and McTaggart, 1992).

### 3.1. Planning

The investigation into the knowledge and understanding of Type 2 drugstore entrepreneurs regarding the GPP criteria was assessed by comparing the self-assessment conducted by the entrepreneurs for their 2022 license renewal applications with the assessment conducted by officers. Additionally, an investigation was carried out to



identify the problems and the readiness of drugstores to meet the assessment criteria. Following the analysis of the situations and identified problems, the results were used to formulate guidelines for the development of Type 2 drugstores to ensure compliance with the GPP standards.

### 3.2. Acting

To establish guidelines for the development of Type 2 drugstores, an academic meeting was arranged. The aim of this meeting was to educate entrepreneurs, cultivate their positive attitudes towards drug laws, and enhance their understanding of the GPP assessment criteria using straightforward and easily comprehensible media with clear examples. Additionally, a focus group session was conducted to facilitate the exchange of opinions aimed at devising guidelines for the development of Type 2 drugstores.

### 3.3. Observing

Opinion data were gathered, and mutual agreement was made in the focus group discussions between the drugstore entrepreneurs and the officers in order to develop the drugstores according to the GPP guidelines as set in the development guidelines for all drugstores to have the same standard and equality throughout the province.

### 3.4. Reflecting

The assessment was performed again by the officers. The 1st officer assessment and 2nd officer assessment were compared to assess the performance of the Type 2 drugstores according to the development guidelines. The results were analyzed and concluded, and opinions were reflected for being continuously used in the next cycle of the Type 2 drugstore development.

## 4. Data analysis

For the quantitative data analysis, statistics such as percentages and standard deviations were used.

Additionally, consistency analysis between the entrepreneurs' self-assessment and the assessment conducted by the officers under Drug Act B.E. 2510 (1967) was assessed using the Kappa statistic by Landis and Koch. Kappa values were interpreted as follows:  $Kappa < 0.00$ , 0.00-0.20, 0.21-0.40, 0.41-0.60, 0.61-0.80, and 0.81-1.00, representing consistency levels of inconsistency, slight, fair, moderate, strong, and almost perfect, respectively (Pasunon P, 2015).

According to the GPP assessment criteria, drugstores were required to have a mean score in each category not lower than 70% without any critical defects. A paired t-test was conducted to compare the means, according to the GPP criteria, between the officers' assessments before and after receiving the development guidelines. Qualitative data obtained from the focus group discussions, including content and details, were analyzed using Content analysis. The statistics were performed using the STATA program.

## Results

### 1. Planning

1.1 General information of all Type 2 drugstores in Udon thani Province

Table 1 presents general information of all Type 2 drugstores in Udon Thani Province. Most licensees of Type 2 drugstores were male (75.00%) at the age of 60 – 69 years (35.00%). Most entrepreneurs were licensees who did not operate as practitioners (75.00%), and most practitioners graduated the training programs for practitioners (65.00%), followed by midwife/nursing entrepreneurs (35.00%) respectively. Most drugstores were located in different districts (52.50%). The business operation period was mostly 35 – 39 years (70.00%), followed by 30 – 34 years (20.00%), and 20 – 24 years (5.00%) respectively.

**Table 1.** General information of all Type 2 drugstores in Udon Thani Province (N=40)

General information	Number of drugstores	Percentage
<b>Gender of licensees</b>		
- Male	30	75.00
- Female	10	25.00
<b>Age of licensees (years)</b>		
- < 39 years	1	2.50
- 40-49 years	4	10.00
- 50-59 years	9	22.50
- 60-69 years	14	35.00
- 70-79 years	12	30.00
<b>Characteristics of entrepreneurs</b>		
- Licensees did not operate as practitioners	30	75.00
- Licensees operate as practitioners	10	25.00
<b>Characteristics of practitioners</b>		
- Graduated the training programs for practitioners	26	65.00
- Midwife/nursing entrepreneurs	14	35.00
<b>Location of drugstores</b>		
- Different districts	21	52.50
- Urban district	19	47.50
<b>The business operation period</b>		
- > 40 years	1	2.50
- 35-39 years	28	70.00
- 30-34 years	8	20.00
- 25-29 years	1	2.50
- 20-24 years	2	5.00

### 1.2 Knowledge and Understanding Situations of Type 2 Drugstore Entrepreneurs According to the GPP Criteria

According to the study on the situations of the Type 2 drugstores according to the GPP criteria as shown in Table 2, when considering the mean score of the entrepreneurs' self-assessment in each category, it was found that the highest mean score was found in Category 1 of place 97.47 points, followed by Category 3 of personnel 96.04 points, Category 2 of equipment 95.00 points, Category 4 of 93.38 drug quality points, and the lowest

score in Category 5 of pharmaceutical service 90.36 points. Regarding the scores of the officers' assessment in each category, the highest mean score was found in Category 2 of equipment 75.00 points, followed by Category 1 of place 71.66 points, and Category 3 of personnel 69.37 points, Category 5 of pharmaceutical service 53.21 points respectively, and the lowest score in Category 4 of drug quality 45.19 points. In the mean comparison between the entrepreneurs' self-assessment and the officers' assessment in each category, the differences were found with the highest mean difference in Category 4 of drug

quality 48.19 points, followed by Category 5 of pharmaceutical service 37.16 points, Category 3 of personnel 26.67 points, Category 1 of place 25.81 points, and the least mean difference in Category 2 of equipment 20.00 points. The overall mean of the entrepreneurs' self-assessment in all 5 categories was 94.45 points whereas the overall mean of the officers' assessment was 62.89 points, indicating that entrepreneurs' self-assessment was higher than the officers' assessment at 31.56 points.

Furthermore, in considering consistency between the entrepreneurs' self-assessment and the officers'

assessment, the consistency was found at the slight level in Category 1 of place (Kappa = 0), at the fair consistency level in Category 2 of equipment (Kappa = 0.25), at the inconsistency level in Category 3 of personnel (Kappa = -0.05), at the slight consistency level in Category 4 of drug quality (Kappa = 0.01), and at the slight consistency level in Category 5 of pharmaceutical service (Kappa = 0.02). The overall consistency of the assessment in all 5 category was at the slight level (Kappa = 0).

**Table 2.** Mean score and consistency comparison between self-assessment and the officers' assessment (N=40)

GPP criteria	Mean (SD)		$\Delta$ Mean	Kappa	95%CI	P-value*
	Self-assessment	the 1 <sup>st</sup> officer assessment				
Category 1 of place	97.47 (5.65)	71.66 (16.09)	25.81	0	N/A	N/A
Category 2 of equipment	95.00 (12.05)	75.00 (26.95)	20.00	0.25	(0.06 - 0.44)	0.01*
Category 3 of personnel	96.04 (9.43)	69.37 (15.72)	26.67	-0.05	(-0.21 - 0.11)	0.73
Category 4 of drug quality	93.38 (9.10)	45.19 (15.23)	48.19	0.01	(-0.01 - 0.02)	0.37
Category 5 of pharmaceutical	90.36 (10.64)	53.21 (15.38)	37.16	0.02	(-0.01 - 0.04)	0.27
<b>Total of 5 category</b>	<b>94.45 (5.89)</b>	<b>62.89 (11.83)</b>	<b>31.56</b>	<b>0</b>	<b>N/A</b>	<b>0.50</b>

$\Delta$ mean, mean difference; \* P-value <0.05; Kappa

### 1.3 Readiness and Problems of the Type 2 Drugstores to Comply with the GPP Criteria

Table 3 shows the results of the 1st GPP assessment by the officers. According to the GPP criteria, to pass the assessment, the mean score in each category must not be lower than 70%. It was found that the criteria which the drugstores least passed was Category 4 of drug quality with only 5.00% of the passing drugstores. The problem was mostly found in arrangement of a drug inspection and supervision system. The drug entrepreneurs did not have knowledge and understanding about arrangement of a recalled drug quality inspection and supervision system before sales. They did not know how to arrange a system for storing drug procurement documents

to be accurate and up to date, and they did not know how to manage a system on complaints about drugstores and reports about defects in drug quality, safety, and effectiveness. The next problem was in Category 5 of pharmaceutical service with 10% of the passing drugstores. The problem was mostly found in preparation of patient screening and referral forms, as well as in the reporting of adverse drug reactions resulting from the use of health products. Moreover, the problem was in arrangement of learning media and advertisement according to laws with consent of the practitioners. The next problems were in Category 1 of place and Category 2 of equipment with 45% of the passing drugstores. The problems mostly found in Category 1 were in regular and up-to-date temperature

control and record, and drug placement according to drug types with drug labels to show drug categories according to academic principles. The problems mostly found in Category 2 were availability and accessibility of equipment such as weighing device, height gage, and fire distinguisher. The category which the drugstores mostly passed the criteria was Category 3 of personnel with 50% of the passing drugstores. The problem was found in the licensees and practitioners' knowledge and understanding about drug laws which were inconsistent and not up to date. As the training courses for practitioners in modern drugstores which were

arranged by Food and Drug Administration in 1984 and 1992 are only for packed drugs, not for packed non-dangerous or non-specially controlled drugs. At present, there are no additional training courses to educate about drug laws of FDA for Type 2 drugstores. In addition, drugstore entrepreneurs become elderly and have difficulty in accessing up-to-date information so they need help from the provincial public health to educate them about current drug laws, different forms according to the GPP assessment, and information system.

**Table 3.** The results of the 1<sup>st</sup> GPP assessment by the officers 1 (N=40)

GPP criteria	Number of drugstores		Most problems founded
	Passed	Failed	
Category 1 of place	18 (45.00)	22 (55.00)	<ul style="list-style-type: none"> <li>• Temperature control and record</li> <li>• Drug placement according to drug types</li> </ul>
Category 2 of equipment	18 (45.00)	22 (55.00)	<ul style="list-style-type: none"> <li>• Availability and accessibility of equipment</li> </ul>
Category 3 of personnel	20 (50.00)	20 (50.00)	<ul style="list-style-type: none"> <li>• Knowledge and understanding about drug laws which were inconsistent and not up to date</li> </ul>
Category 4 of drug quality	2 (5.00)	38 (95.00)	<ul style="list-style-type: none"> <li>• Arrangement of a drug inspection and supervision system</li> <li>• System for storing drug procurement documents</li> <li>• System on complaints about drugstores and reports about defects in drug quality and safety</li> </ul>
Category 5 of pharmaceutical	4 (10.00)	36 (90.00)	<ul style="list-style-type: none"> <li>• Preparation of patient screening and referral forms</li> <li>• Preparation of adverse drug reaction report</li> <li>• arrangement of learning media and advertisement according to laws</li> </ul>

## 2. Acting

### Guidelines for Development of the Type 2 Drugstores

According to Table 4, the problems found in compliance to the GPP were analyzed and assessed. The problems which need to be solved by the provincial public health are in 3 issues: 1) knowledge of drug laws and the assessment criteria which are accurate, clear and up to

date; 2) information system for exchanging information, suggestion, and consultation between drugstore entrepreneurs and the officers; and 3) forms and documents used in the assessment. These problem issues are used to determine guidelines for the Type 2 drugstores according to the GPP criteria with the same equal standards throughout the province as follows.





2.1 Arrange meetings for participatory development of the Type 2 drugstores towards the GPP standards.

2.2 Support accurate standard documents and forms used in the assessment to reduce the burden and difficulty of the entrepreneurs in preparing documents in a standard form of publication and electronic document as follows: 1) identification badges indicating profession or academic standing; 2) form of job description and roles of practitioners and employees; 3) form of recalled or changed drugs quality inspection before sales; 4) record of complaints and report to relevant organizations; 5) appropriate form of patient screening and referral; and 6) form to report adverse drug reaction from using health products and report to relevant organizations.

2.3 Arrange an online channel for giving advice one by one through Line Official as an individual personal consultation between drugstore entrepreneurs and the officers in order to make the entrepreneurs to feel comfortable and trust to receive advice. Moreover, the officers can give advice accurately, thoroughly, quickly and conveniently; reduce inconsistency of communication; and give advice about authorized channel of health product inspection through the website of Food and Drug Administration, Ministry of Public Health.

Regarding the meeting arrangement for participatory development of the Type 2 drugstores to

comply with the GPP criteria, the licensees or practitioners of all 40 Type-2 drugstores in Udon Thani Province are invited to the meeting. The meeting contains 2 main activities as follows.

**Activity 1:** An academic training is to give knowledge and enhance positive attitudes of the drugstore entrepreneurs by using simple and easy-to-understand media and presenting with clear simple examples. The academic contents consist of 2 parts: 1) drug laws, and 2) the GPP assessment criteria. The focus is on the entrepreneurs' participation in considering each assessment criterion together, asking questions, or exchanging opinions with the lecturers immediately.

**Activity 2:** A focus group is for exchanging opinions for determining guidelines for development of the Type 2 drugstores and mutual agreements between the entrepreneurs and the officers with the same standard throughout the province. The issues in the focus group are 1) explanation of situations and problems found in compliance to the GPP criteria; 2) suggestion on a channel for giving advices through Line Official and authorized channels for health product inspection; 3) support documents and forms used in the GPP assessment with correct and complete explanation on preparation for assessment; 4) opinion exchange and mutual agreement.

**Table 4.** Guidelines for Development of the Type 2 Drugstores

The problems found in compliance to GPP	Guidelines for development
1. knowledge of drug laws and the assessment criteria officers	● Arrange meetings for participatory development of the Type 2 drugstores towards the GPP standards
2. Forms and documents used in the assessment	● Support accurate standard documents and forms
3. Information system for exchanging information, suggestion, and consultation	<ul style="list-style-type: none"> <li>● Arrange an online channel for giving advice through Line Official as an individual personal consultation</li> <li>● Give advice about authorized channel of health product inspection</li> </ul>

### 3. Observing

Results of focus group in determining the guidelines for development of the Type 2 drugstores Guidelines

According to the focus group for exchanging opinions in determining the guidelines for participatory development of the Type 2 drugstores according to the GPP criteria, the set issues were found as follows.

3.1 Situations and problems of drugstores according to the GPP criteria

The entrepreneurs perceived situations and problems in Type 2 drugstores which needed to be in compliance with the GPP criteria. They also agreed and consented to change as prescribed by laws.

3.2. The GPP assessment criteria and requirements

The entrepreneurs recognized the advantages of their participation in training sessions about knowledge of drug laws and the GPP assessment criteria. They considered details of assessment criteria, asked questions, and exchanged opinions so they got more accurate and clearer understanding about guidelines for being compliant and qualified accurately and completely. The entrepreneurs provided recommendations to establish ongoing training programs aimed at acquiring current and legally compliant information.

3.3 Guidelines for drugstore development

The entrepreneurs agreed to the guidelines for participatory development, which emphasized equality, fairness, and consistent standards throughout the province, ensuring that people could access the full benefits. Documents for assessment were provided to alleviate the burden and difficulty faced by the entrepreneurs, along with online channels for receiving personal advice. As a result, the entrepreneurs developed better attitudes and perspectives, enabling them to develop drugstores in compliance with the laws.

3.4 Mutual agreement in developing drugstores according to the GPP criteria.

The entrepreneurs agreed together to implement according to the GPP assessment criteria accurately and comprehensively, and they would implement according to the guidelines within 2 months. Nevertheless, two drugstores opted for business termination due to their inability to meet the requirements of the GPP assessment criteria.

### 4. Reflecting

Results of Guidelines for Development of the Type 2 Drugstores

Table 5 presents the results of the 2nd officer assessment after implementing according to the guidelines for development of 38 Type-2 drugstores who were compliant to the GPP criteria. It was found that the category with the highest mean score was Category 2 of equipment 100.00 points, (SD = 0.00), followed by Category 1 of place 95.39 points (SD = 8.10), Category 4 of drug quality 93.97 points (SD = 11.86), Category 3 of personnel 92.76 points (SD = 13.59) respectively, and the least mean score in Category 5 of pharmaceutical service 91.48 points (SD = 10.72). When considering the difference of the mean score in each category between the assessing results before and after using the development guidelines, the category with the highest mean difference score was Category 4 of drug quality 48.72 points, followed by Category 5 of pharmaceutical service 37.80 points, Category 3 of personnel 23.90 points, Category 2 of equipment 23.68 points respectively, and the least mean difference score in Category 1 of place 23.66 points. After using the guidelines for development of the Type 2 drugstores, the mean scores increased in all categories with statistical significance ( $p < 0.05$ ). When considering the mean scores of 5 categories, it was found the assessing result after using the development guidelines was at the mean of 94.72 points (SD = 7.89) higher than the assessing result before using the development guidelines mean = 63.16 points (SD = 11.78) at the mean difference of 31.56 points (95% CI = 28.02 - 35.09) with statistical significance ( $p < 0.05$ ).



**Table 5.** Mean score and consistency comparison between the 1<sup>st</sup> and 2<sup>nd</sup> officer assessment (N=38)

GPP criteria	Mean score of officer assessment (SD)		Δ Mean	95%CI	P-value
	The 1 <sup>st</sup> assessment	The 2 <sup>nd</sup> assessment			
Category 1 of place	71.72 (16.45)	95.39 (8.10)	23.66	18.51 - 28.82	<0.001
Category 2 of equipment	76.32 (24.39)	100.00 (0.00)	23.68	15.67 - 31.70	<0.001
Category 3 of personnel	68.86 (15.94)	92.76 (13.59)	23.90	18.20 - 29.61	<0.001
Category 4 of drug quality	45.24 (15.63)	93.97 (11.86)	48.72	43.35 - 54.09	<0.001
Category 5 of pharmaceutical	53.68 (15.59)	91.48 (10.72)	37.80	32.23 - 43.38	<0.001
<b>Total of 5 category</b>	<b>63.16 (11.78)</b>	<b>94.72 (7.89)</b>	<b>31.56</b>	<b>28.02 - 35.09</b>	<b>&lt;0.001</b>

Δmean, mean difference; \* P-value <0.05; t-test

## Discussion and Conclusion

According to the knowledge and understanding situation of the Type 2 drugstore entrepreneurs according to the GPP criteria in Udon Thani Province, the drugstore entrepreneurs' self-assessment results were different from the officers' results. The consistency of both assessments in each category was at the inconsistency level to the slight consistency level in all dimensions, except the category of equipment which was at the fair consistency level. Regarding readiness of the drugstores according to the assessment criteria in each category, it was found that the category with the highest readiness and mostly passing the criteria was Category 3 of personnel and the least readiness and least passing the criteria in Category 4 of drug quality. The problems mostly found were the drugstore entrepreneurs' lack of knowledge and understanding about drug laws and the GPP assessment criteria which were inconsistency and inaccurate. Most entrepreneurs were elderly with difficulty to access up-to-date information. Therefore, the entrepreneurs need help and support from the provincial public health office in educating about accurate and up-to-date drug laws, documents and forms used in the GPP assessment, and information system to access necessary information. This finding is consistent to the study of Sombutpoothon P *et al.*, entitled Participatory Action Research on the Empowerment of Modern

Drugstores for Packaged Non-Dangerous or Non-Specially Controlled Drugs in Chonburi. Their study found that the drugstores had the least readiness to comply with the GPP criteria in Category 4 of drug quality. They found that the entrepreneurs lacked of relevant legal knowledge, had negative attitude towards compliance to the ministerial notification, and lacked of necessary skills for using information technology (Sombutpoothon P *et al.*, 2023).

The problems mostly found from attempting to comply with the GPP criteria in the part of assessment document preparation which needs support and help were as follows. Category 4 was on arrangement of a system for inspecting recalled drug quality before sales, a system for storing legal and up-to-date documents of drug procurement, a system for receiving complaints, and a system for reporting defects in drug quality, effectiveness, and safety. And Category 5 was on preparation for patient screening and referral forms, and report form of adverse drug reaction from using health products; and placement of legal learning media and advertisement to give knowledge. At present, the requirements according to the GPP criteria in Type 2 drugstores are relatively new, and research on compliance with these criteria remains limited. However, when compared to previous investigations into GPP adherence in Type 1 drugstores, which share similarities,

congruence was found in the study of Wientong *et al.*'s., entitled Readiness among Community Pharmacists in Chiang Mai to Comply with the Ministerial Declaration on Licensing and Requirements on Premises, Instruments and Good Pharmacy Practice. They found that the least readiness was in pharmaceutical service which mostly needed help especially in a process to prevent repeated drug allergy, a process to screen and refer patients, and a process to monitor adverse drug reaction and report to related organizations. For development, the drugstores need to collaborate with each other to develop the drugstores to comply with the legal criteria (Wientong P *et al.*, 2017).

Regarding the guidelines for development of the Type 2 drugstores, based on the problem assessment and analysis, help and support are needed by basing on the same standards throughout the province for people to receive legal drug service with health safety. The development guidelines are formulated as follows. 1) Arrange a meeting for participatory development of the Type 2 drugstore to comply with the GPP criteria by focusing on giving knowledge and enhancing positive attitudes of the drugstore entrepreneurs in terms of drug laws and the requirement of the GPP criteria. In addition, the focus group should be arranged to exchange opinions and set mutual agreement with the same standards throughout the province. 2) Support documents and forms. And 3) arrange an online channel through Line Official. This finding is consistent to the study of Sombutpoothon P, entitled Factors on Drugstore with Good Pharmacy Practice to Abide the Criterion of the Quality Pharmacy at Chonburi Province. He found that the guidelines for enhancing and developing modern drugstores to comply with the criterion of the quality pharmacy were in 1) changing attitudes and building positive perspective on good pharmacy practice to abide by the criterion of the quality pharmacy; 2) building entrepreneurship incentives; 3) being admired through

public relation when passing the criterion of quality pharmacy; 4) increasing public relation channels to create understanding among public about difference between quality pharmacy and general pharmacy; 5) developing processes, procedures, and conditions through participation of organizations and networks. And 6) supporting necessary documents and forms as required by the assessment criteria (Sombutpoothon P, 2021).

Regarding the results from the development of the Type 2 drugstores, all drugstore entrepreneurs agreed with the participatory development of the Type 2 drugstores with equality and the same standard through out the province. The entrepreneurs were able to comply with the all accurate the GPP assessment criteria within 2 months. However, 2 drugstores notified business dissolution since they failed to comply with the GPP criteria. Regarding the 2nd officer assessment after using the development of Type 2 drugstores, the mean score of each category was higher than 90% in all categories with statistical significance ( $p < 0.05$ ). This finding is consistent to the study of Dhanasilangkura W., on Strategies in Strengthening Drugstores to Fulfill Good Pharmacy Practice in Udon Thani Province by using the quality cycle of PDCA: 1) publicize the GPP assessment criteria, 2) use a channel of Line Official for questions and answers, and 3) support equipment required by the GPP criteria. It was found that from using the guidelines, all drugstores could pass the GPP assessment with the mean score in each category more than 90% (Dhanasilangkura W, 2024). This finding is consistent to the study of Chuntaravichit U, entitled Development Model to Upgrade Good Pharmacy Practice (GPP) Standards in Drugstore, Singburi by using the quality cycle of PDCA. In the 2nd standard assessment, all drugstores could pass the assessment criteria with the overall mean score of quality assessment higher than the



mean score before the joining the development process, and the mean score in each category also increased at the statistical significance level of 0.01 (Chuntaravichit U, 2020).

The participatory development of the drugstores according to the concept of Kemmis and McTaggart relies on participation of everyone in building knowledge and exchanging opinions freely and equally in order to drive collaborative operation for development and improvement. The focus is on building understanding about the assessment criteria, exchanging knowledge and opinions together, and building good attitudes and relationship between the drugstore entrepreneurs and the officers, resulting in the mean score of the drugstores in the GPP criteria not lower than 70% without critical effects. Therefore, all Type 2 drugstores in Udonthai Province could successfully pass the GPP assessment criteria according to the ministerial notification. This finding is consistent to the study of Thongyoung P on Development of Drugstores to Good Pharmacy Practice by Participatory Action Research in Samutsongkhram Province. The focus was on a process to apply knowledge and participation in every step from building understanding, setting goal together, sharing knowledge, and make better change. The sample group agreed with the equal development with the same standard throughout the province. As a result, drugstores could be developed to the GPP standards from 2 to 22 drugstores with the 2nd overall assessment score of all existing drugstores increased with statistical significance ( $p$ -value < 0.001) (Thongyoung P *et al.*, 2018).

This research on development of the Type 2 drugstores should be further studied continuously on development of drugstore potentials and quality according to the development guidelines for enabling entrepreneurs to run business with sustainable quality and standard. Food and Drug Administration, drugstore associations and clubs

should determine policies for participatory development of the Type 2 drugstores to comply with the GPP standards with the focus on exchanging opinions and considering development guidelines together for protecting consumers to receive legal drugs with quality and safety from drugstores.

## Acknowledgements

This research was supported by the Health Consumer Protection Program. The researchers are grateful to Mr. Manot Nakhawatchana, Pharmacist and Expert Level Head of the Health Consumer Protection and Pharmacy Department at the Udon Thani Provincial Public Health Office, and Ms. Kanokporn Thanmaneesin, Pharmacist and Professional Level Staff at the Khonkaen Provincial Public Health Office, as well as all Drug and Narcotic Officers of the Udon Thani Provincial Public Health Office for their advice and support. The participation of entrepreneurs from Type 2 drugstores who followed established guidelines was also crucial to the successful completion.

## References

- Chuntaravichit U. Development model to upgrade good pharmacy practice (GPP) standards in drug store Singburi. *SHJ*. 2020; 29: 119-28.
- Dhanasilangkura W. Strategies in Strengthening Drugstores to Fulfill Good Pharmacy Practice in Udon Thani. *TJPP*. In press 2024.
- Drug Act, B.E. 2510. Royal Gazette No. 84, Part 101 special (Oct 20, 1967).
- Kemmis, S., & McTaggart, R. (1992) *The Action Research Planner* (3rd ed.). Geelong: Deakin University Press.



- Medicines Regulation Division of Food and Drug Administration Thailand. Statistics of pharmaceutical business licenses 2022. [Online]. [cited 2023 March 10]. Available from: <https://www.fda.moph.go.th/sites/drug/Shared%20Documents/Statistic/Licensee-20221223.pdf>.
- Notification of Food and Drug Administration on Criteria, methods and conditions for passing the assessment according to Good Pharmaceutical Practices regulation. B.E. 2016. Royal Gazette. No.133, Part 123D Special (May 27, 2016).
- Notification of Food and Drug Administration on the renewal of a Drug license Narcotics drug in category 3 Psychotropic Substances in category 3 or 4 for using in 2023. (Sep 23, 2022).
- Notification of the Ministry of Public Health on Determine the number of premises for selling Packaged modern medicines that are not Dangerous drugs or Specially Controlled Drugs in each province. B.E. 2005. Royal Gazette. No.122, Part 25D Special (Mar 23, 2005).
- Notification of the Ministry of Public Health on places equipment and methods of community pharmacy in a place that sells packed modern medicines that are not dangerous drugs or specially controlled drugs according to the Drug Law, B.E. 2021. Royal Gazette. No.138, Part 281D Special (Nov 16, 2021).
- Pasunon P. Evaluation of inter-rater reliability using Kappa statistics. Journal of Faculty of Applied Arts, King Mongkut's University of Technology North Bangkok. 2015; 8: 2-20.
- Public Health Ministerial Rule in 2013 on license application and licensing of modern drug selling. Royal Gazette No.130, Part 126A (Dec 27, 2013).
- Sombutpoothon P, Reamrimmadun Y, Polnok A. Participatory action research on the empowerment of modern drugstores for packaged non-dangerous or non-specially controlled drugs in Chonburi. *TJPP*. 2023; 15(2): 347-359.
- Sombutpoothon P. Factors on drug store with good pharmacy practice to abide the criterion of the quality pharmacy at Chonburi province [master thesis]. Pitsanulok: Naresuan University; 2021.
- The Office of Community Pharmacy Accreditation Thailand. History of Community Pharmacy Development. [online] 2023 [cited Jul 7, 2023]. Available from: <https://papc.pharmacycouncil.org/index.php?option=aboutus&subpage=history>.
- Thongyoung P, Komwuthikarn K. Development of drugstores to good pharmacy practice by participatory action research in Samutsongkhram Province. *Thai Food and Drug Journal*. 2018; 25: 39-48.
- Wientong P, Chinwong D, Chinwong S, Vacharachaisurapol P, Dutjanuthat A, Supakul S. Readiness among community pharmacists in Chiang mai to comply with the ministerial declaration on licensing and requirements on premises, instruments and good pharmacy practice. *TJPP*. 2017; 9(1): 92-102.